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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

EXELIXIS, INC., Plaintiff, v. MSN LABORATORIES PRIVATE LIMITED and MSN PHARMACEUTICALS, INC., Defendants.	C.A. No. 19-2017 (RGA) (SRF) **CONSOLIDATED** REDACTED - PUBLIC VERSION

PLAINTIFF'S OPENING BRIEF IN SUPPORT OF ITS MOTION TO EXCLUDE THE OBVIOUSNESS OPINIONS OF SALVATORE LEPORE AND JONATHAN STEED AND ANY REFERENCE TO THEM BY OTHER EXPERTS

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I. INTRODUCTION

In their reports, MSN's invalidity experts Salvatore Lepore and Jonathan Steed purport to offer testimony concerning the obviousness of the patents-in-suit; however, neither expert identifies any specific combination of references on which their obviousness opinions are based, let alone articulates why a POSA would have been motivated to combine the specific disclosures in any such combination or would have had a reasonable expectation of achieving the claimed inventions using any such combination. Drs. Lepore and Steed instead offer a menu of combinations that collectively represent at least millions if not billions of alternative options. That foundational problem underlying Drs. Lepore's and Steed's obviousness opinions is compounded by their reliance on irrelevant evidence related to the inventors' path to the invention and commercial (i.e., non-scientific), hindsight-driven motivations to explore unpatented compounds.

Because Dr. Lepore's and Dr. Steed's reliance on millions or billions of unspecified combinations is a flawed methodology that is unhelpful to the finder of fact and fails to put Exelixis fairly on notice of any *specific* combinations, their obviousness opinions should be excluded in their entirety. Fed. R. Civ. P. 26(a)(2)(B). To establish obviousness, MSN is required to demonstrate that a POSA would have been motivated to combine particular disclosures within specific prior art references with a reasonable expectation of success. *ProBatter Sports, LLC v. Sports Tutor, Inc.*, 680 F. App'x 972, 975 (Fed. Cir. 2017) (a showing of obviousness requires a defendant to "articulate a clear theory of obviousness" with a specifically identified obviousness combination, and criticizing reference to "a slew of references in ten separate obviousness combinations, some of which combined as many as five different references"); *Intendis GMBH v. Glenmark Pharms. Ltd.*, 117 F. Supp. 3d 549, 590-91 (D. Del. 2015), *aff'd sub nom. Intendis GMBH v. Glenmark Pharms. Inc., USA*, 822 F.3d 1355 (Fed. Cir.

2016) (rejecting expert's "cursory" bucket-based motivation to combine arguments related to "group-wise" obviousness combination because it failed to articulate a specific motivation to combine); *see also Motorola Mobility, LLC v. Int'l Trade Comm'n*, 737 F.3d 1345, 1350 (Fed. Cir. 2013) (affirming rejection of obviousness argument based on "conclusory and generalized sentences" in which party "did not clearly identify the scope and content of the prior art that it was asserting, or provide any argument that certain prior art references render a specific claim obvious"). By providing a vast menu of options rather than addressing motivation to combine and reasonable expectation of success with respect to any particular combinations of prior art, Drs. Lepore and Steed have presented obviousness analyses that are fundamentally flawed. Moreover, to the extent either or both experts attempt to narrow their opinions at trial by focusing on one or more subsets of combinations that were not specifically discussed in their reports, any such opinions should be excluded based on their failure to disclose them in their expert reports as required by Fed. R. Civ. P. 26(a)(2)(B).

To the extent their opinions are not excluded in their entirety, Drs. Lepore and Steed should be precluded from offering any testimony that seeking freedom to operate would have provided a motivation to pursue the claimed invention or that the path taken by the inventors is supportive or confirmatory of alleged obviousness, because it is legally improper to consider either of these factors in assessing obviousness.

II. LEGAL STANDARDS

MSN bears the burden of establishing that its expert testimony is admissible. *See Bourjaily v. United States*, 483 U.S. 171, 175 (1987). Rule 702, which governs admissibility, "embodies a trilogy of restrictions on expert testimony: qualification, reliability and fit." *Schneider ex rel. Est. of Schneider v. Fried*, 320 F.3d 396, 404 (3d Cir. 2003); *see also* Fed. R. Evid. 702; *Daubert*, 509 U.S. at 589-597. These three requirements ensure the testimony is

"helpful[] to the trier of fact." *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 744 (3d Cir. 1994). Likewise, expert testimony that fails to apply the correct legal standard "is not relevant and, ergo, non-helpful." *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 591 (1993). Separately, an expert's report must also provide a "complete statement of all [the] opinions" to be expressed and "the basis and reasons" underlying the opinions. *Magnetar Techs. Corp. v. Six Flags Theme Parks, Inc.*, 61 F. Supp. 3d 437, 441 (D. Del. 2014); Fed. R. Civ. P. 26(A)(2)(B)(i).

III. BACKGROUND

There are three patents at issue in this case: U.S. Patent Nos. 7,579,473 ("the '473 patent"); 8,497,284 ("the '284 patent"); and 8,877,776 ("the '776 patent"). Broadly speaking, the '473 patent's claims cover the novel compound cabozantinib, including pharmaceutical compositions and salts; the '284 patent's claims cover methods of treating certain cancers using cabozantinib or its pharmaceutically acceptable salts; and the '776 patent's claims cover a novel crystalline form of the cabozantinib (L)-malate salt, Form N-2.

Dr. Lepore offers an opinion that (1) the claims covering the cabozantinib compound (claims 1-7 of the '473 patent) and (2) the "cabozantinib element" of the claims covering methods of treatment using cabozantinib (claims 1, 8, 18, and 23 of the '284 patent) would have been obvious based on a large menu of combinations without discussing motivation to combine or reasonable expectation of success with respect to any particular combination. *See* Ex. A ("Lepore Opening Report") ¶¶ 7-9, 204. With respect to the cabozantinib element, MSN's expert Dr. Mega relies solely on Dr. Lepore's flawed analysis to support his opinion that the asserted claims of the '284 patent are obvious. *See* Ex. B ("Mega Opening Report") ¶¶ 185-194; Ex. C ("Mega Tr.") 48:8-51:18.

Dr. Steed offers an opinion that claims 1-2 of the '776 patent would have been obvious based on a large menu of combinations without discussing motivation to combine or reasonable

expectation of success with respect to any particular combination. Ex. D ("Steed Opening Report") ¶¶ 123, 215-218.

IV. THE COURT SHOULD EXCLUDE THE OBVIOUSNESS OPINIONS OF DRS. LEPORE AND STEED AND ANY REFERENCE TO THEM BY OTHER EXPERTS

Drs. Lepore and Steed have set forth opinions contending that the patents-in-suit are obvious, but neither expert has identified any specific combination of references, any motivation to combine any specific disclosure within a combination of references, or any basis for a POSA to have had a reasonable expectation of achieving the claimed inventions based on any specific combination. *ProBatter Sports*, 680 F. App'x at 975; *Intendis*, 117 F. Supp. 3d at 590-91; *see also Motorola Mobility*, 737 F.3d at 1350. Therefore, the obviousness opinions of Drs. Lepore and Steed are fundamentally flawed and should be excluded in their entirety.

A. Drs. Steed and Lepore Have Not Identified Any Specific Combinations

The obviousness opinions of Drs. Steed and Lepore should be excluded because neither expert sets forth or analyzes motivation or reasonable expectation of success with respect to any specific obviousness combination. Identifying a specific combination of references is a prerequisite to demonstrating obviousness. *See ActiveVideo Networks, Inc. v. Verizon Commc'ns, Inc.*, 694 F.3d 1312, 1327 (Fed. Cir. 2012) (criticizing expert testimony which had "no relation to any specific combination of prior art elements . . . from specific references"); *Innogenetics, NV v. Abbott Laboratories*, 512 F. 3d 1363, 1373 (Fed. Cir. 2008) (affirming district court's exclusion of expert's "vague and conclusory obviousness testimony which did not offer any motivation for one skilled in the art to combine the particular references he cites in order to practice the claimed method" because expert's report did not state "how or why a person ordinarily skilled in the art would have found the claims of the '704 patent obvious in light of some combination of those particular references"). Obviousness requires that a POSA would

have selected *specific* teachings and combined them. *Id*. Because neither expert identified a specific combination of references in any of their reports—and confirmed as much at their depositions—their testimony is not based on the correct legal standard and therefore inadmissible. *Daubert*, 509 U.S. at 593; *Oxford Gene Tech. Ltd. v. Mergen Ltd.*, 345 F. Supp. 2d 431, 437-438, 440-441 (D. Del. 2004) (limiting expert testimony on motivation to combine to the generalized motivation offered in the expert report and excluding portions of the expert's opinion on invalidity because opinion was based on "conclusion that a combination of some or all of" five prior art references rendered challenged patent obvious and because expert failed to "undertake the required element-by-element comparison to show that each and every limitation in the asserted claims of the [challenged] patent is present in a combination of prior art references" and failed to "specifically discuss which elements combine to form the basis for his opinion."); *see Asahi Glass Co., Ltd. v. Guardian Indus. Corp.*, 2011 WL 4459606, at *2 (D. Del. Sept. 26, 2011) ("An expert witness who has been proffered to opine on the validity of a patent must follow the required steps of a validity analysis, that is, to construe the asserted claims of the patent to determine their subject matter, and then to perform a limitation-by-limitation comparison of each claim to each prior art reference.").

1. Dr. Lepore Discloses More than 15 Million Potential Obviousness Combinations

Dr. Lepore's opinion that the cabozantinib compound is obvious relies on a host of references he discusses generically, without identifying any specific combinations. In his Opening Report, Dr. Lepore contends:

> A POSA would not need to combine every prior art reference discussed in Section VIII above, and those discussed in Section VIII of the Mega opening Report, to arrive at cabozantinib. Rather, it is my opinion that cabozantinib would have been obvious in view of WO '660 when combined with one or more references from each of the categories listed below ("Cabozantinib References"):

- Any one or more of the prior art regarding c-Met's role in various Cancers, i.e.: Ueki, Maulik, Shawver, or Traxler (discussed in the Mega Opening Report, Section VIII.A);

- Any one or more of the prior art related to selecting a lead compound, i.e.: the '746 patent, Onderwater 1998, Onderwater 1999, Lipinski, Ghose, or Egan;

- Any one or more of the prior art related to modifying the lead compound, i.e.: Williams, the '992 patent, Nes, McMorris, Kelner 1995, Kelner 2000, the '746 patent, Salaün, Wessjohann, the '410 patent, Fry, Allen, NCT '830, or NCT '051.

Lepore Opening Report ¶ 204. By referring to combinations of "one or more" references from each of those three categories, Dr. Lepore has identified 15,481,935 potential combinations that he contends may render the compound cabozantinib obvious.[1] Dr. Lepore further opines that "claims 1-7 of the '473 patent would have been obvious in view of the Cabozantinib References alone or in combination with Remington, Berge, and/or Tong," resulting in even more unspecified obviousness combinations. Lepore Opening Report ¶ 205. In his opening and reply reports concerning validity, Dr. Lepore did not identify any specific combination of references to support his conclusion. At his deposition, Dr. Lepore confirmed that his obviousness opinions were based on the combination of WO '660 and one or more references from the three categories identified in his report, and did not provide any more specific combinations. Ex. E ("Lepore Tr.") 11:15-15:9, 16:1-17:17 ("Yes, these are the references that I rely on in making my

[1]Dr. MacMillan calculated the number of potential combinations in his rebuttal report. *See* Ex. F ("MacMillan Rebuttal Report") ¶ 319 n.459. Dr. Lepore has not provided an alternative number for the combinations he is proposing. *See* Ex. G ("Lepore Reply Report") ¶ 82.

Category	Number of references in category	Ways to choose X references from category, where X =														Total # options per category
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	
1	4	4	6	4	1											15
2	6	6	15	20	15	6	1									63
3	14	14	91	364	1001	2002	3003	3432	3003	2002	1001	364	91	14	1	16383
Total number of combinations, choose one or more from each of three categories:																15,481,935

obviousness arguments. These are the obviousness combinations, as I indicated in [paragraph 204]."); *see also* Lepore Reply Report ¶ 82.

As noted above, Dr. Mega's opinion on the obviousness of the '284 patent's claims is predicated on Dr. Lepore's analysis of the obviousness of the cabozantinib compound. *See* Mega Opening Report ¶¶ 185-194; Mega Tr. 48:8-51:18. To the extent Dr. Mega's opinion relies on Dr. Lepore's analysis, his opinion likewise improperly relies on millions of obviousness combinations.

2. Dr. Steed Discloses More than 60 Billion Potential Obviousness Combinations

Dr. Steed's opinions that claims 1 and 2 of the '776 patent are obvious rely on even more references, similarly presented in generic buckets with no specific combinations identified. Dr. Steed contends that Form N-2 cabozantinib (L)-malate "would have been obvious in view of the '928 Application and/or the '140 publication and/or the '564 patent when combined with one or more references" from each of two groups of references that he describes as Category 2 and 3 references. Steed Opening Report ¶ 216. The three categories of references are set forth in ¶ 216 of Dr. Steed's report and reproduced below:

Category 1 References (3)	Category 2 References (16)	Category 3 References (17)
• '564 patent; and/or • '928 application; and/or • '140 publication	• Bighley; and/or • Berge; and/or • Paulekuhn; and/or • '905 patent; and/or • '198 patent; and/or • '338 patent; and/or • Bighley; and/or • '835 patent; and/or • '621 patent; and/or • '107 patent; and/or • '307 patent; and/or; • '070 patent; and/or • '407 patent; and/or • '483 patent; and/or • 'Tong; and/or • 'Fieser	• Remington's 2000; and/or • Shekunov; and/or • Yu; and/or • Caira; and/or • Hornedo; and/or • Gu; and/or • Vippagunta; and/or • Byrn; and/or • Haleblian 1969; and/or • Haleblian 1975; and/or • Threlfall; and/or • McCrone; and/or • Guillory; and/or • Brittain; and/or • Desiraju; and/or • FDA Guideline; and/or • ICH Guideline

Steed Opening Report ¶ 216. By using "and/or" and referring to "one or more" references from each of three categories, Dr. Steed identifies 60,128,165,895 potential combinations that he contends may render claims 1 and 2 of the '776 patent obvious.[2] *See* Ex. H ("Trout Rebuttal Report") ¶ 236. In his opening and reply reports concerning validity, Dr. Steed did not identify any specific combination of references to support his conclusion. At his deposition, Dr. Steed confirmed that he was offering the opinion that "form N-2 would be obvious in view of the 928

[2]This calculation is performed the same way as that for Dr. Lepore's analysis.

		Ways to choose X references from category, where X =																	
Category	Number of references in category	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Total # options per category
1	3	3	3	1															7
2	16	16	120	560	1820	4368	8008	11440	12870	11440	8008	4368	1820	560	120	16	1		65535
3	17	17	136	680	2380	6188	12376	19448	24310	24310	19448	12376	6188	2380	680	136	17	1	131071
Total number of combinations, choose one or more from each of three categories:																			60,128,165,895

application and/or the 140 publication and/or the 564 patent when combined with one or more references from section 9B and 9C." Ex. I ("Steed Rough Tr.") 25:21-27:10 (testifying that "you can combine [the references] in multiple ways" and suggesting that each combination "would be a specific combination").

B. Drs. Steed and Lepore Have Not Identified Any Motivation to Combine or Reasonable Expectation of Success With Respect to Any Specific Combination of Disclosures

Drs. Steed and Lepore have also failed to identify any motivation to combine or reasonable expectation of success with respect to any specific combination of disclosures within their vast menus of options. Conclusory statements "with no explanation" cannot "support a finding that there would have been a motivation to combine." *TQ Delta, LLC v. CISCO Sys., Inc.*, 942 F.3d 1352, 1359 (Fed. Cir. 2019) (quoting *In re Van Os*, 844 F.3d 1359, 1361-62 (Fed. Cir. 2017)).

In terms of a motivation to combine as to claims 1-7 of the '473 patent and the cabozantinib element of claims 1, 8, 18, and 23 of the '284 patent, Dr. Lepore provides only the conclusory statement that "a POSA would have been motivated to combine the prior art disclosures to make cabozantinib, or a pharmaceutically acceptable salt of cabozantinib, with a reasonable expectation of success in obtaining a compound that inhibits c-Met tyrosine kinase and, as Dr. Mega has opined . . . that would be useful in treating certain cancers such as renal cancer." Lepore Opening Report ¶ 203. Although Dr. Lepore's report refers to a POSA's "motivation" to pursue certain research avenues and make certain modifications to the compound, he nowhere provides reasons that a POSA would have been motivated to combine any specific disclosures within the vast number of references he identifies with a reasonable expectation of success. *See* Lepore Opening Report ¶¶ 206, 208-209, 212, 216, 224, 225, 234, 237-238, 240, 241, 246, 253-254, 257.

Like Dr. Lepore, Dr. Steed fails to identify any motivation to combine any references in his various lists with any reasonable expectation of success. Dr. Steed does not solve the problem by referring to a generalized motivation to improve solubility. *See, e.g.*, *Amerigen Pharm. Ltd. v. UCB Pharma GmbH*, 913 F.3d 1076, 1087 (Fed. Cir. 2019) (a generalized motivation to enhance bioavailability is not sufficient to support an opinion of obviousness); *see* Steed Opening Report ¶ 219.

Dr. Lepore's and Dr. Steed's failure to disclose any specific obviousness combinations prejudices Exelixis because Exelixis and its experts have been unable to prepare any response to any such specific combinations or motivations to combine specific references. The purpose of Rule 26's requirement that an expert report provide "a complete statement of all opinions the witness will express and the basis and reasons for them" (Fed. R. Civ. P. 26(A)(2)(B)(i)) is to prevent "the party against whom the excluded witnesses would have testified" from experiencing "prejudice or surprise," *ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 298 (3d Cir. 2012). MSN cannot present the millions of possible obviousness combinations offered by Drs. Lepore and Steed at trial. Given the sheer volume of combinations, Exelixis cannot feasibly prepare responses to all of them, thus harming its ability to prepare for trial. The Lepore and Steed opinions do not adequately disclose MSN's invalidity positions and should be excluded.

V. AT A MINIMUM, DR. LEPORE AND DR. STEED SHOULD BE PRECLUDED FROM OFFERING TESTIMONY AT TRIAL REGARDING SPECIFIC COMBINATIONS NOT DISCUSSED IN THEIR EXPERT REPORTS.

At a minimum, the Court should preclude Drs. Lepore and Steed from testifying that the asserted claims of the patents-in-suit are rendered obvious in view of any combination of references that has not been specifically discussed. MSN was required to provide "a complete statement of all opinions the witness will express and the basis and reasons for them," Fed. R. Civ. P. 26(A)(2)(B)(i), yet it failed to identify and explain any specific combinations of

references and should not be allowed to identify them now. Allowing MSN to generically disclose an enormous number of obviousness combinations and then, after the close of expert discovery when Exelixis and its experts can no longer respond, identify specific disclosures within a narrowed combination of references to move forward with would unfairly prejudice Exelixis.[3] For the same reasons, to the extent Dr. Mega's analysis relies on Dr. Lepore's improper obviousness analysis, it too should be excluded.

VI. DR. LEPORE'S AND DR. STEED'S TESTIMONY CONCERNING FREEDOM TO OPERATE AND THE INVENTORS' PATH SHOULD BE EXCLUDED

To the extent their opinions are not precluded in their entirety, Dr. Lepore's and Dr. Steed's opinions concerning freedom to operate and the path taken by the inventors should be excluded because they are legally improper. It is well-established that the "inventor's own path itself never leads to a conclusion of obviousness." *Millennium Pharms., Inc. v. Sandoz Inc.,* 862 F.3d 1356, 1367 (Fed. Cir. 2017). And "the general commercial motivation to develop novel compounds does not suffice 'to show that the prior art would have suggested making the specific molecular modifications necessary to achieve the claimed invention.'" *Takeda Pharm. Co. v. Torrent Pharm. Ltd.*, No. Civil Action No. 17-3186 (SRC) (CLW) (consolidated), 2020 WL 549594, at *15 (D.N.J. Feb. 4, 2020) (quoting *Amerigen Pharm. Ltd. v. UCB Pharma GmBH*, 913 F.3d 1076, 1089 (Fed. Cir. 2019)). Yet, MSN's experts resort to both.

For example, Dr. Steed's report contains ten pages' worth of opinion about the inventors' path, complete with subheadings like "Exelixis' preparation of the (L)-Malate salt of

[3]To the extent MSN contends that Exelixis failed to put MSN on notice of its experts' inadequate disclosure of obviousness combinations until after the close of expert discovery, that is unfounded and no excuse. Both of Exelixis' experts, in rebuttal, brought this issue to Dr. Steed's and Dr. Lepore's attention, and Dr. Steed and Dr. Lepore still failed to identify specific combinations on reply or in any way that would have allowed Exelixis to explore those specific combinations at their depositions. *See* Trout Rebuttal Rep. ¶¶ 236-237; MacMillan Rebuttal Rep. ¶¶ 318-319.

Cabozantinib as Part of a Routine Salt Screen" and "Exelixis obtains Form N-2 of Cabozantinib (L)-Malate as Part of a Routine Salt Screen," and citing to testimony from Dr. Shah and Dr. Lamb. Steed Opening Report ¶¶ 266-297. Dr. Lepore's report likewise contains a four-page section devoted to explaining how "Information Obtained in Discovery Further Supports My Opinions," citing to testimony from Dr. Bannen, Dr. Xu, and Dr. Mann. Lepore Rep. ¶¶ 300-311.

Dr. Lepore and Dr. Steed insist that their obviousness opinions are not based on this inventor testimony or Exelixis' development path, but that it merely "supports [their] opinions." Lepore Opening Rep. ¶ 300; Steed Opening Report ¶ 266. But such a statement begs the question of why the testimony and Exelixis' internal documents were included in their reports at all. If they did not rely on the inventors' path in forming their opinions, they should not be permitted to testify about it because it is not within the scope of their opinions; if they did rely on the inventors' path in forming their opinions, their opinions are based on unreliable methods that are contrary to established law and should be excluded for that reason. *See* Fed. R. Evid. 702 (allowing opinion testimony only if "the testimony is the product of reliable principles and methods").

Moreover, Dr. Lepore explicitly relies on commercial motivations as part of his obviousness opinions, even where the scientific motivations pointed in the other direction. *See* Lepore Opening Report ¶ 224 (contending that "concerns about restrictions on freedom to operate" would have motivated a POSA to choose a malonamide-type compound over a urea-type compound, even though malonamides are "metabolically unstable" (Lepore Opening Report ¶ 235) and ureas were not (Lepore Tr. 207:3-21)); *see also* Lepore Opening Report ¶ 241 (again relying on "freedom to operate issues and/or the possibility of obtaining their own intellectual

property"). That too is contrary to Federal Circuit law, rendering those portions of Dr. Lepore's opinions inadmissible as the product of unreliable methods.

VII. CONCLUSION

For the reasons stated above, Dr. Lepore's and Steed's testimony should be excluded in its entirety. At a minimum, Drs. Lepore and Steed should be precluded from offering opinions at trial: (A) related to specific combinations not discussed in their expert reports; and (B) that freedom to operate would have provided a motivation to pursue the claimed invention or that the path taken by the inventors is supportive or confirmatory of alleged obviousness. Furthermore, other experts for MSN should be precluded from referencing or relying on any opinions or portions o f opinions from Dr. Lepore or Dr. Steed that are excluded.

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CERTIFICATE OF SERVICE

I hereby certify that on March 23, 2022, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on March 23, 2022, upon the following in the manner indicated:

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